K110936

## 5. 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

JUN 10 2011

Submitter:
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Date Summary was Prepared: 01-April-2011

Device Proprietary Name: DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit
Classification Name: Catheter, Hemodialysis, Implanted
Device Product Code: MSD

Predicate Device(s): The DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit is substantially equivalent to the following device:

| Device Name | Manufacturer | 510(k) No. |
|---|---|---|
| AngioDynamics® DuraMax® Catheter and Procedure Kit | AngioDynamics® | K101843, cleared 10/20/2010 |

**Device Description:**
The DuraFlow™ 2 Chronic Hemodialysis Catheter is a dual lumen, 15.5FR catheter and is available in multiple lengths, in straight configurations. The catheter lumens are D-shaped and made from radiopaque Carbothane.

The distal end design is a fixed length step tip with side-holes. The distal venous lumen extends past the arterial lumen. The proximal section of the device contains a fixed polyester cuff that allows for tissue in growth for long term placement, an integrated bifurcation hub, suture wing, and extension leg set with color-coded occlusion clamps and luer connectors (red and blue for the arterial and venous lumens respectively). The lumen priming volumes are printed on the ID tags clamps. The procedure kit includes the necessary accessories to correctly insert the catheter.

**Statement of Intended Use:**
The intended use of the DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit is identical to the intended use of the predicate, DuraMax Hemodialysis Catheter and Procedure Kit that was cleared via K101843.

Specifically, the AngioDynamics, Inc. DuraFlow™ 2 Chronic Hemodialysis Catheter is intended for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternative insertion sits include the subclavian vein as required. Catheters greater than 40cm are intended for femoral vein placement. The catheter is indicated for >30 days long-term placement.

**Substantial Equivalence:**
As compared to the predicate DuraMax Chronic Hemodialysis Catheter and Procedure Kit (K101843) , the DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit incorporates a revision to the catheter tip as well as modification to the sidehole configuration.

**Discussion of Nonclinical Tests:**
The safety and performance of the DuraFlow™ 2 Chronic Hemodialysis Catheter has been substantiated through extensive non-clinical testing including shaft tensile strength, joint strength, leakage, flow rate, mechanical hemolysis and kit component compatibility.

Results of testing show that the DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit can reliably perform as a conventional hemodialysis catheter for obtaining blood access for hemodialysis and apheresis. No new questions of safety or effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 10 2011

Mr. David A. Greer
Manager, Regulatory Affairs
Angiodynamics, Inc.
14 Plaza Drive
LATHAM NY 12110

Re: K110936
Trade/Device Name: DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: April 1, 2011
Received: April 4, 2011

Dear Mr. Greer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

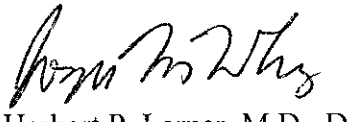
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

**4. INDICATIONS FOR USE STATEMENT**

# Indications for Use

510(k) Number (if known): New Application K110936

Device Name: DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit

Indications for Use: The DuraFlow™ 2 Chronic Hemodialysis Catheter and Procedure Kit is indicated for use in attaining long-term vascular access for hemodialysis and apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternative Insertion sites include the subclavian vein as required.

Catheters greater than 40 cm are intended for femoral vein insertion.

This catheter is indicated for > 30 days long-term placement.

| Prescription Use ✓ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110936